Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Original) An apparatus for the continuous production of lipid vesicles by in-line mixing, said apparatus comprising:

(a) a lipid phase storage means capable of being maintained at a set temperature and a first pressurized transfer means for transferring the lipid phase from the storage means;

(b) an aqueous phase storage means capable of being maintained at a set temperature and a second pressurized transfer means for transferring the aqueous phase from the storage means;

(c) a mixing device comprising: a first metering system for receiving the lipid phase from the first pressurized transfer means; a second metering system for receiving the aqueous phase from the second pressurized transfer means; a pre-mixing system for preparing a pre-mixed formulation; a third pressurized transfer means for transferring the lipid phase from the first metering system to a first inlet orifice on the pre-mixing system and a fourth pressurized transfer means for transferring the aqueous phase from the second metering system to a second inlet orifice on the pre-mixing system; a mixer for preparing a mixed formulation comprising lipid vesicles, having a mixing chamber and an optional means for determining the optical properties of the mixed formulation; a means for transferring the pre-mixed formulation from the outlet orifice of the pre-mixing system to the mixing chamber; and an optional means for applying ultrasonic energy to the pre-mixing system, the mixing chamber or both; and

(d) a dispensing means for transferring the mixed formulation from the mixing chamber into a storage chamber.

2. (Original) The apparatus of Claim 1 wherein said lipid vesicles are multilamellar or oligolamellar.

3. (Original) The apparatus of Claim 1 which further comprises a means for homogenization or sonication located between the dispensing means and the storage chamber.

4. (Original) The apparatus of Claim 2 wherein said lipid vesicles are unilamellar.

5. (Original) The apparatus of Claim 1 wherein the lipid phase comprises an active agent.

6. (Original) The apparatus of Claim 1 wherein the lipid phase storage means is capable of being maintained at a set temperature by a first temperature control means and the aqueous phase storage means is capable of being maintained at a set temperature by a second temperature control means.

7. (Original) The apparatus of Claim 6 wherein said lipid phase storage means is maintained at a temperature within the range of about 20 to 80°C.

8. (Original) The apparatus of Claim 6 wherein said aqueous phase storage means is maintained at a temperature within the range of about 20 to 80°C.

9. (Original) The apparatus of Claim 1 wherein the means for determining the optical properties of the mixed formulation is configured so as to control the first and second temperature control means and the first and second metering systems.

10. (Original) The apparatus of Claim 1 which further comprises additional storage means for a second lipid phase, a pre-mixed lipid phase-aqueous phase mixture or a pre-formed lipid vesicle phase.

11. (Original) The apparatus of Claim 1 wherein the lipid phase and aqueous phase storage means further comprise means for replenishing the lipid and aqueous phases.

12. (Original) The apparatus of Claim 1 which operates under pressures within the range of about 10 to 90 psia.

13. (Original) The apparatus of Claim 1 wherein the fluid flow rate of the lipid phase is about 3 to 200 cm^3/sec and the fluid flow rate of the aqueous phase is about 5 to 300 cm^3/sec.

14. (Original) The apparatus of Claim 1 wherein the mixer is a static mixer.

15. (Original) The apparatus of Claim 14 wherein the static mixer is a laminar division type inline mixer.

16. (Original) The apparatus of Claim 1 wherein the mixer further comprises a means for controlling the temperature of the mixing chamber.

17. (Original) The apparatus of Claim 16 wherein the means for controlling the temperature of the mixing chamber maintains the temperature of the chamber within the range of about 20 to 80°C.

18. (Original) The apparatus of Claim 1 wherein the mixer further comprises a means for controlling the degree and rate of mixing within the mixing chamber.

19. (Original) The apparatus of Claim 1 wherein the storage chamber is part of a packaging machine.

20. (Original) The apparatus of Claim 1 wherein the dispensing means further comprises a means for controlling the rate at which the formulation is transferred from the mixing chamber into the storage chamber.

21. (Original) The apparatus of Claim 1 wherein the mixing device further comprises a means for controlling the temperature of the device.

22. (Original) The apparatus of Claim 21 wherein the device is maintained at a temperature within the range of about 20 to 80°C.

23. (Original) The apparatus of Claim 1 wherein each metering system comprises a precise metering pump and a manifold.

24. (Original) The apparatus of Claim 23 wherein each pump and manifold have a plurality of inlet and outlet means, where each pump inlet means communicates with a manifold outlet means and each pump outlet means communicates with a manifold inlet means; where each pump inlet means is 90° out of phase with the preceding pump inlet means and the successive pump inlet means, and the manifold further comprises a manifold outlet orifice and a manifold inlet orifice.

25. (Original) The apparatus of Claim 24 wherein the inlet orifice of a first manifold is in communication with the first pressurized transfer means and the outlet orifice of a first manifold is in communication with the third pressurized transfer means, the inlet orifice of a second manifold is in communication with the second pressurized transfer means and the outlet orifice of a second manifold is in communication with the fourth pressurized transfer means.

Claims 26-33. Canceled.

34. (Original) A method for the continuous production of lipid vesicles by in-line mixing, said method comprising:

(a) preparing a lipid phase and storing the lipid phase in a first storage means that is maintained at a set temperature;

(b) preparing an aqueous phase and storing the aqueous phase in a second storage means that is maintained at a set temperature;

(c) combining the lipid and aqueous phases by means of a mixing device having first and second metering systems, a pre-mixing system and a mixer, by: transferring the lipid phase from the first storage means to the first metering system by a first pressurized transfer means and transferring the aqueous phase from the second storage means to the second metering system by a second pressurized transfer means; transferring the lipid phase from the first metering system to a first inlet orifice in the pre-mixing system by a third pressurized transfer means and transferring the aqueous phase from the second metering system to a second inlet orifice in the pre-mixing system by a fourth pressurized transfer means; wherein the lipid phase and aqueous phases are transferred to the pre-

mixing system with a high velocity creating turbulent flow; combining the lipid and aqueous phases in the pre-mixing system by shear mixing under conditions to insure that the lipid phase becomes fully hydrated by the aqueous phase to form a pre-mixed formulation; and transferring the pre-mixed formulation from an outlet orifice of the pre-mixing system to the mixer;

(d) forming a mixed formulation containing lipid vesicles, in the mixer by causing the pre-mixed formulation to traverse the mixer;

(e) optionally measuring the optical properties of the lipid vesicles; and

(f) dispensing the mixed formulation from the mixer into a storage chamber, into a means for further modification of the properties of the lipid vesicles, or into a means of packaging the mixed formulation.

35. (Original) The method of Claim 34 wherein said lipid vesicles are multilamellar.

36. (Original) The method of Claim 34 which further comprises a homogenization or sonication step after the dispensing step.

37. (Original) The method of Claim 36 wherein said lipid vesicles are unilamellar.

38. (Original) The method of Claim 34 wherein the lipid phase comprises an active agent.

39. (Original) The method of Claim 34 wherein said first storage means is maintained at a temperature within the range of about 20 to 80°C.

40. (Original) The method of Claim 34 wherein said second storage means is maintained at a temperature within the range of about 20 to 80°C.

41. (Original) The method of Claim 34 wherein the step of measuring optical properties is by means of an optical transmission sensing device using a photoresistor or phototransistor, which provides a control signal to a controlling computer or other process control device.

42. (Original) The method of Claim 34 which further comprises the addition of a second lipid phase, a pre-mixed lipid phase-aqueous phase mixture or a pre-formed lipid vesicle phase.

43. (Original) The method of Claim 34 wherein the first and second storage means are continuously replenished with the lipid and aqueous phases, respectively.

44. (Original) The method of Claim 34 wherein the pressures are within the range of about 10 to 90 psia.

45. (Original) The method of Claim 34 wherein the fluid flow rate of the lipid phase is about 3 to 200 cm^3/sec, and the fluid flow rate of the aqueous phase is about 5 to 300 cm^3/sec.

46. (Original) The method of Claim 34 wherein mixer is maintained at a temperature within the range of about 20 to 80°C.

47. (Original) The method of Claim 34 wherein each metering system comprises a precise metering pump and a manifold, where each pump and manifold have a plurality of inlet and outlet means, each pump inlet means communicates with a manifold outlet means and each pump outlet means communicates with a manifold inlet means, and the manifold further comprises a manifold outlet orifice and a manifold inlet orifice; the method further comprising:

transferring the lipid phase to the inlet orifice of a first manifold by the first pressurized transfer means and simultaneously transferring the aqueous phase to the inlet orifice of a second manifold by the second pressurized transfer means;

transferring the lipid phase from the plurality of outlet means of the first manifold to the plurality of inlet means of a first pump and simultaneously transferring the aqueous phase from the plurality of outlet means of the second manifold to the plurality of inlet means of the second pump;

transferring the lipid phase from the plurality of outlet means of the first pump to the plurality of inlet means of the first manifold and transferring the aqueous phase from

the plurality of outlet means of the second pump to the plurality of inlet means of the second manifold; and

transferring the lipid phase from the outlet orifice of the first manifold by the third pressurized transfer means and simultaneously transferring the aqueous phase from the outlet of the second manifold by the fourth pressurized transfer means.

48. (Original) The method of Claim 47 wherein the lipid phase and aqueous phases are transferred to the pre-mixer a precise ratio.

49. (Original) The method of Claim 47 wherein the lipid phase and aqueous phases are transferred to the pre-mixer in a near pulse-less flow.

Claims 50-57. Canceled.